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10/616,622

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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04/13/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/616,622 | Applicant(s) LAFONTAINE, DANIEL M. | |
| | Examiner DIANE YABUT | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-29 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 16-29, 31-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 01/22/2010.

Claims 1-14, 16-29, and 31-41 are pending in the application. Claims 11-12 and 14 are withdrawn from consideration.

Response to Arguments

1. Applicant's arguments filed 01/22/2010 have been fully considered but they are not persuasive.
2. Applicant argues that modifying Huebsch with Hart would not have occurred to one of ordinary skill in the art since the additional force required to facilitate the deformation of the actuator end 232 of Hart would render the device unsuitable for its intended use since the pulling forces may promote undesirable bleeding and tissue damage. However, the teaching of Hart's deformable actuator end is not evidence of excessive pulling forces, since "it can be removed from the body passage without affecting the outside diameter of the access device near the incision in the body passage (col. 3, lines 14-19). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the withdrawing step of Huebsch et al. with the use of a collapse actuator with a deformable distal end in response to sufficient proximal force, as taught by Hart, in order to facilitate retraction and removal of the actuator without the need for its rotation to ensure passage through the distal aperture.
3. Applicant also argues that it is not clear how the device of Huebsch would be modified to include the pile backing of Lafontaine, and it appears as though the hooks of

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the pile backing would not engage the pile when collapsed due to intervening tissue.

The examiner clarifies that the pile backing of Lafontaine would be placed on the exterior surface or struts of Huebsch, and agrees that tissue in between the proximal struts and the distal struts would appear to prevent the hooks from contacting the pile. However, the combination device of Huebsch and Lafontaine would still have the capability of the hooks entangling the backing when in a collapsed position (as in Figure 17 of Huebsch), without interfering tissue present, and therefore reads on the claim limitations. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable pile backing with hooks that entangle the backing when moved from a non-collapsed to collapsed position, as taught by Lafontaine et al., to the closure component of Huebsch et al. in order to quickly close the blood vessel while leaving the patient minimally impacted (col. 4, lines 57-67) and further maintain the collapsed configuration of the closure component.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10, 13, 16-21, 23-29, and 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Huebsch et al.** (U.S. Patent No. **6,312,446**) in view of **Hart** (U.S. Patent No. **5,846,251**) and **Lafontaine et al.** (U.S. Patent No. **5,964,782**).

Huebsch et al. disclose an elongate delivery member **40** and inserting through a body opening a closure component through the delivery member which includes a collapsible backing or support **200** with proximally facing tissue engaging hooks **270** disposed thereon and being generally conically shaped and having a center portion **216** distally spaced from the periphery of the backing in the non-collapsed, non-deployed position, withdrawing the closure component proximally relative to the opening such that the tissue engaging hooks engage tissue adjacent the opening, applying proximally directed force to a collapse actuator wire **230** releasably coupled to the collapsible backing with a distal end **232** received with and extending distal to a distal aperture **234** of the collapsible backing to thereby collapse the backing to a collapsed, deployed position in which the center portion is moved proximally toward the backing periphery to form a generally disc shape and the hooks engage the tissue, and disconnecting the collapse actuator from the collapsible backing permitting the detachable distal end to pass proximally through the distal aperture and the collapsed backing, and then disconnecting the closure component from the distal end of the delivery member by rotating the collapse actuator (Figures 5a-5b, 14-17 and 21-22; col. 6, line 43 to col. 7, line 50).

Huebsch et al. disclose disconnecting the collapse actuator detachable distal end **232** from the collapsible backing by rotating the actuator so that it fits through distal aperture **234**, and therefore the collapse actuator is connected or disconnected to the backing depending on its position relative to the distal aperture of the backing (Figures

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16-17; col. 6, lines 54-65), which allows for expanding and collapsing of the backing before being detached.

However, Huebsch et al. do not disclose the collapse actuator detachable distal end assuming a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator in order to permit the detachable distal end to pass proximally through the distal aperture.

Hart teaches a collapse actuator having a detachable distal end **54** (which is first joined to collapsible element **43** and is received with a distal aperture near **85**; see Figures 4-6) configured to assume a deformed profile ("reduce the profile or diameter") solely in response to a sufficient proximal force ("tension") applied to the collapse actuator, the deformed profile permitting the detachable distal to pass proximally through the distal aperture and thereby detach from the collapsible element (see Figures 5-7; col. 10, lines 28-34). Another embodiment shown in Figures 28E-28H shows that proximal force to collapse actuator **300** causes its detachable distal end **301** to assume a deformed profile (to be "folded back onto itself during withdrawal," col. 13, lines 41-47) in order to permit the distal end to pass proximally, or to be mechanically released, through a distal aperture near **325**. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the withdrawing step of Huebsch et al. with the use of a collapse actuator with a deformable distal end in response to sufficient proximal force, as taught by Hart, in order to facilitate retraction and removal of the actuator without the need for its rotation to ensure passage through the distal aperture.

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Huebsch et al. also lack the collapsible backing being made of pile or fabric, wherein the pile tissue engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position.

Lafontaine et al. teach a bioabsorbable pile backing **344** with tissue or adventitia engaging hooks that entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position to retain the backing in a collapsed configuration (Figures 34A-34C; col. 17, lines 38-43 and col. 18, lines 24-29). The engaging hooks are oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable pile backing with hooks that entangle the backing when moved from a non-collapsed to collapsed position, as taught by Lafontaine et al., to the closure component of Huebsch et al. in order to quickly close the blood vessel while leaving the patient minimally impacted (col. 4, lines 57-67) and further maintain the collapsed configuration of the closure component.

Lastly, although Huebsch et al. teach biocompatible materials (col. 3, line 57 to col. 4, line 17), bioabsorbable materials are not expressly disclosed.

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3. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Huebsch et al.** (U.S. Patent No. **6,312,446**) in view of **Hart** (U.S. Patent No. **5,846,251**) and **Lafontaine et al.** (U.S. Patent No. **5,964,782**), as applied to claim 21 above, and further in view of **Luscombe et al.** (U.S. Patent No. **5,683,418**).

Huebsch et al., Hart, and Lafontaine et al. disclose the claimed invention as discussed above, including the collapse actuator having a distal end that is detachable to the distal end of a closure component, except for the collapse actuator having a frangible connection.

Luscombe et al. teach a detachable distal end **108** of an actuator **107** that is frangible due to withdrawal tension (see abstract, Figures 18-20). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the combined invention of Huebsch et al., Hart, and Lafontaine et al. disclose by providing a frangible connection, as taught by Luscombe et al., in order to facilitate separation from the closure component which is well known in the art as a detachment mechanism (col. 3, lines 13-16).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Trainer
TC 3700
April 11, 2010